

### **REMARKS/ARGUMENTS**

The present application has been reviewed in light of the Office Action mailed May 14, 2004. Claims 16-19, 22-33 and 36-44 are pending in the application, claims 16, 22, 30, 36 and 44 having been amended herein, and claims 20, 21, 34 and 35 having been cancelled herein. Reconsideration of the present application, as amended, is respectfully requested.

In view of the Examiner's earlier restriction requirement, Applicant reserves the right to present previously withdrawn claims 1-15 and 45-50 in a divisional application.

The disclosure has been objected to as containing various minor informalities identified by the Examiner. The specification has been amended in the manner indicated above in order to correct and/or remove the various minor informalities identified by the Examiner.

The drawings have been objected to for failing to show every feature of the invention specified in the claims, namely the locking structure defined in claims 23 and 37. The specification has been amended at page 6 to further describe an exemplary locking structure and FIG. 1 has been amended to illustrate the locking structure in the form of a tether 15 which is fixedly secured to the distal end of radially expandable sleeve 12 and extends axially through sleeve 12. Accordingly, in view of the amendments to the specification and to FIG. 1, the objection to claims 23 and 37 has been overcome.

In amended FIG. 5, the previously omitted element numerals 12 and 14' have been added thereto.

Claims 16-43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (U.S. Patent 5,201,756) in view of Makower et al. (U.S. Patent 5,380,290). It is respectfully submitted that claims 16-43, as amended herein, are allowable over Horzewski et al. in view of Makower et al.

It is respectfully submitted that Horzewski et al. taken alone or in proper combination with Makower et al. fails to teach or suggest amended independent claims 16 and 30.

Independent claim 16 presently recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration, and inserting into the radially expandable sleeve a dilator to expand the expansible sleeve to a larger configuration to provide an access lumen to the blood vessel.

Independent claim 30 presently recites a method for establishing vascular access, including the steps of, *inter alia*, positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration, ***wherein the radial expandable sleeve comprises a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof***; introducing a dilator over the guidewire and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter; and removing the dilator wherein the expandable sleeve retains the larger diameter.

In particular, Horzewski et al. discloses an inner tubular element 11 containing a slit 13 that extends the length thereof. Slit 13, in conjunction with the elasticity of outer tubular element 14 enables shaft sections 5 and 6, and delivery channel 15 within these sections, to expand radially in response to the passage of devices of relatively large profile therethrough. The opposing surfaces of inner tubular element 11 are superimposed upon one another, as shown in

FIG. 1B. This configuration enables inner tubular element 11 to expand radially and still remain circumferentially intact. Inner tubular element 11 is made from a medium density polyurethane.

It is respectfully submitted that Horzewski et al. fails to disclose inserting into the radially expandable sleeve a dilator to expand the expansible sleeve to a larger configuration to provide an access lumen to the blood vessel, as called for in claim 16, or a radially expandable sleeve including a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof, as called for in claim 30.

The Examiner relies on Makower et al. solely for the proposition of forming a tissue tract prior to the introduction of a guidewire therethrough in order to obtain the advantage of facilitating the introduction of the guidewire. Makower et al. fails to remedy the deficiencies of Horzewski et al. in that Makower et al. fails to teach or disclose a radially expandable sleeve including a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof, as called for in claims 16 and 30.

It is therefore respectfully submitted that, in view of the amendments to claims 16 and 30, and in view of the arguments presented above, that claims 16 and 30 are allowable over Horzewski et al. in view of Makower et al.

Claim 44 was rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. in view of Makower et al. as applied to claim 16 above, and further in view of Shockey et al. (U.S. Patent 4,994,033). It is respectfully submitted that claim 44, as amended herein, is allowable over Horzewski et al. in view of Makower et al. and further in view of Shockey et al.

It is respectfully submitted that Horzewski et al. does not disclose the positioning of a guidewire percutaneously through the skin and into the blood vessel of the patient and then positioning an expandable sleeve over the guidewire into the blood vessel.

Additionally, it is further respectfully submitted that none of the prior art references, taken alone or in any proper combination, address minimizing the size of the percutaneous tissue tract as well as minimizing the trauma to the blood vessel wall.

Accordingly, it is respectfully submitted that Horzewski et al. taken alone or in proper combination with Makower et al. and Shockey et al. fails to teach or suggest amended independent claim 44.

Independent claim 44 presently recites, *inter alia*, an improved method for establishing vascular access, wherein the improvement includes introducing a radially expandable sleeve over the guidewire prior to introducing the dilator, ***wherein the radial expandable sleeve comprises a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof***, and thereafter introducing the dilator through the sleeve, whereby axial forces on the tissue from the dilator are reduced.

For the reasons presented above with regard to the patentability of claims 16 and 30 over Horzewski et al. in view of Makower et al., claim 44 is also allowable over Horzewski et al. in view of Makower et al.

The Examiner relies on Shockey et al. solely for the proposition of introducing a diagnostic or therapeutic device over a guidewire and through a guide catheter so that the device may still be guided even after it emerges from the guide catheter. Shockey et al. fails to remedy the deficiencies of Horzewski et al. and Makower et al. in that Shockey et al. fails to teach or disclose a radially expandable sleeve including a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof, as called for in claim 44.

Makower et al. discloses introducing a needle 14 and outer layer 28 into a vessel, introducing a “dilator” 24 and then removing the needle 14 and sleeve 28. Makower et al. fails

to disclose introducing an expandable sleeve over a guidewire and using a dilator to expand the sleeve.

It is therefore respectfully submitted that, in view of the amendments to claim 44, and in view of the arguments presented above, that claim 44 is allowable over Horzewski et al. in view of Makower et al. and further in view of Shockey et al.

It is respectfully submitted that the construction of expandable sleeves as tubular braids is not obvious. It is further submitted that none of the references relied upon by the Examiner teach or even suggest the use of a radially expandable tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof, as called for in claims 1, 30 and 44. Accordingly, it would not have been obvious to construct the Horzewski et al. expandable sleeve with a radially expandable tubular braid.

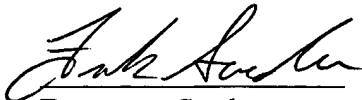
In view of the amendments made to the specification, the drawings and the claims, and in view of the remarks/arguments presented above, it is respectfully submitted that each of the objections and rejections raised in the present Office Action have been overcome.

It is respectfully submitted that none of the references of record, considered individually or in any proper combination, disclose or suggest the present invention as claimed.

Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicants' undersigned attorney at the number indicated below.

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of claims 16-19, 22-33 and 36-44 is earnestly solicited.

Respectfully submitted,

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